DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR CONSOLIDATED MOTION TO DISMISS PLAINTIFFS' COMPLAINTS

All seven complaints[1] before this Court rest on the flawed premise that a company may not freely choose to introduce new products and discontinue old ones if, for any reason, a competitor can allege that they were injured as a result. Plaintiffs do not claim that Defendants prevented them from selling a fenofibrate product and acknowledge that the new TriCor products have improved features over the discontinued formulations. This is fatal to their antitrust claims. Despite Plaintiffs' unhappiness that Abbott and Fournier have stayed one step ahead of the generic manufacturers, the antitrust laws do not obligate Defendants to aid Teva and Impax by continuing to make and sell an old product formulation that is easier for them to copy and sell. Equally unavailing are Plaintiffs' claims that Abbott and Fournier misused the applicable litigation and regulatory processes in defense of their innovations. Plaintiffs' desire for a free pass from competition on their own terms, or relief from the prevailing legal and regulatory framework, is no basis for an antitrust claim.

Plaintiffs' claims distill into two basic categories of allegedly improper conduct. The first category of allegations ("Product Introductions") attacks the right to introduce new TriCor formulations and to discontinue the old TriCor formulations. The second category of allegations

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[1] *See* Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively "Teva") Second Amended Answer, Affirmative Defenses, and Counterclaims ("Teva's Answer" or "Teva Counterclaims") (C.A. 02-1512, D.I. 20); Impax Laboratories, Inc. ("Impax") First Amended Counterclaims ("Impax Counterclaims") (C.A. 03-120, D.I. 9); Walgreen Co., Eckerd Corp., The Kroger Co., Maxi Drug, Inc., Albertson's, Inc., Safeway, Inc., and Hy-Vee, Inc. (collectively "Walgreen") Amended Complaint and Demand for Jury Trial ("Walgreen Complaint") (C.A. 05-340, D.I. 31); CVS Pharmacy, Inc., Rite Aid Corp., Rite Aid Hdqrts. Corp. (collectively "CVS") Amended Complaint ("CVS Complaint") (C.A. 05-340, D.I. 30); Pacificare Health Systems, Inc. First Amended Complaint ("Pacificare Complaint") (C.A. 05-360, D.I. 35); Direct Purchaser Class Plaintiffs' First Amended and Consolidated Class Action Complaint ("Consolidated Direct Purchaser Complaint") (C.A. 05-340, D.I. 29); and End Payor Plaintiffs ("Indirect Purchaser Class") Consolidated Class Action Complaint ("Consolidated Indirect Purchaser Complaint") (C.A. 05-360, D.I. 24). These entities are collectively referred to as "Plaintiffs."

("Litigation Conduct") relates to Abbott and Fournier protecting their intellectual property rights through litigation under the framework established by the patent laws and the Hatch-Waxman Act.

Plaintiffs' Product Introduction claims fail for a number of reasons. Plaintiffs concede, as they must, that Defendants have the right to introduce new TriCor products. Plaintiffs' pleadings further acknowledge that Defendants' new TriCor products had improved features over the versions that they replaced. Plaintiffs are left to allege that the conceded improvements were not great enough to warrant their introduction to the market, thereby providing a basis to sue under the antitrust laws. Courts routinely reject efforts to cast new product introductions as anticompetitive and unlawful.

Plaintiffs alternatively allege that, having introduced new products, Abbott and Fournier had a duty to provide aid and assistance to their competitors either by continuing to sell the old product or by pretending that they were continuing to sell the old product. No case or theory under the antitrust laws would support a cause of action based on the foregoing. First, Plaintiffs cannot allege that any company has been foreclosed from making or selling fenofibrate products by Defendants' new product introductions and the discontinuance of the old versions. As they concede, Teva has been doing so since 2002. Second, truthfully notifying the market generally, and pricing services specifically, that an old product was no longer being sold, and accepting returns of a discontinued product fail to state a claim.

Plaintiffs' Litigation Conduct claims consist of three different allegations: (i) bringing sham patent litigation; (ii) wrongfully listing a patent in the Orange Book; and (iii) committing an actionable antitrust "fraud on the patent office" or *Walker Process*[2] violation in connection with the '881 patent.

This Court already has determined, in effect, that the patent litigations were not a sham. The '405 patent and the '881 patent survived motions for summary judgment and were set for trial. A

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[2] *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965).

limited number of plaintiffs also assert that the prior capsule patent litigation was objectively baseless – although the actual defendants in those cases, Teva and Impax, do not. This Court need do no more than review the district court and Federal Circuit decisions in the case to find Plaintiffs' sham litigation claims inadequate.

Plaintiffs alternative theory is that the tablet litigations were a sham because Defendants allegedly were "aware" that Fournier's patents would later be found unenforceable. Under the guise of alleging sham litigation, Plaintiffs cannot misuse the inequitable conduct defense to circumvent the well-established requirements of the *Walker Process* doctrine.

No Plaintiff has a viable *Walker Process* claim. They either lack standing or have failed to plead antitrust injury. For the same reasons, the Orange Book claims fail.

For the reasons discussed below, Plaintiffs' tort, state antitrust law, and state consumer protection allegations also fail to state a claim.

STATEMENT OF FACTS

I. Defendants' Fenofibrate Capsule Products

In 1997 Fournier granted Abbott a license to the '726 patent for fenofibrate. Consolidated Direct Purchaser Complaint, ¶ 46. Abbott secured FDA approval to launch its first TriCor fenofibrate product, a 67 mg dosage in 1998, and received approval in the following year for a 200 mg dosage. Impax Counterclaims, ¶ 29. As is required by the Hatch-Waxman Act, Abbott identified the relevant patents for its TriCor product in the Orange Book. Teva Counterclaims, ¶ 64; Impax Counterclaims, ¶ 29.

Capitalizing on TriCor's acceptance, certain companies, including Novopharm Ltd. (Teva's predecessor) and Impax, developed a generic fenofibrate capsule. Teva Counterclaims, ¶ 5;

Impax Counterclaims, ¶ 30. Teva and Impax filed ANDAs with Paragraph IV certifications. Teva Counterclaims, ¶ 65; Impax Counterclaims, ¶ 30. Abbott and Fournier asserted the '726 patent in April 2000 against Teva, and in August 2000 against Impax. Teva Counterclaims, ¶ 66; Impax Counterclaims, ¶ 31.

In March 2002, United States District Judge John W. Darrah of the Northern District of Illinois construed the disputed claim terms of the '726 patent. Based on its construction of the disputed claim term "co-micronized fenofibrate," the district court granted Novopharm's motion for summary judgment of non-infringement. *Abbott Labs. v. Novopharm Ltd.*, No. 00 C 2141, 00 C 5094, 01 C 1914, 2002 U.S. Dist. LEXIS 4659 (N.D. Ill. March 20, 2002) (attached as Exhibit 1), *aff'd*, 323 F.3d 1324 (Fed. Cir. 2003).

The FDA granted final approval of Teva's capsule ANDA and Teva began marketing its fenofibrate capsules in April 2002. Teva Counterclaims, ¶ 68. Teva is still selling this product today under the brand name Lofibra®. Teva Counterclaims, ¶ 79. Lofibra is not the only fenofibrate capsule on the market. Reliant also sells a fenofibrate capsule today (Antara), and Impax has FDA approval to market a fenofibrate capsule, but has not exercised its right to do so. Consolidated Direct Purchaser Complaint, ¶ 77; Impax Counterclaims, ¶ 43.

Neither Teva nor Impax suggested during the capsule litigations that Abbott and Fournier had brought their patent infringement claims in bad faith. Nor did the district court or Federal Circuit suggest that the legal dispute over the claim construction of the term "co-micronized fenofibrate" was anything other than a good faith dispute over the appropriate meaning of the term.

II. Defendants' First-Generation Tablets

Long before Teva, Impax, or any other company filed ANDAs for fenofibrate capsules, Fournier and Abbott were continuing to work to improve the performance of their TriCor product. Fournier invested in technology from Pharma Pass in 1996, leading to the development of a new

fenofibrate tablet in 160 mg and 54 mg dosages that received FDA approval in September 2001 (the "Tablet Introduction"). Teva Counterclaims, ¶¶ 70, 140.

As even Plaintiffs concede in their Amended Complaints, the new TriCor tablet was an improvement over the old TriCor capsules. Teva Counterclaims, ¶ 71; Impax Counterclaims, ¶ 33. In addition to being a tablet, which many patients prefer, it had better bioavailability, meaning that patients could take a lower dosage of the active ingredient. This new tablet also had an expanded FDA label, showing that it was indicated to raise HDL (so-called good cholesterol). Teva Counterclaims, ¶ 71; Impax Counterclaims, ¶ 33. Although the bioavailability of the tablet was better than the capsule, to get the full benefits of the product patients were still required to take the product only with food. Teva Counterclaims, ¶ 98.

After receiving approval for the new TriCor tablet, Abbott discontinued selling the existing 200 mg and 67 mg capsule products. Abbott advised the National Drug Data File ("NDDF"), a private database with comprehensive descriptive, pricing, and clinical information on drugs available to customers, that is was no longer selling the capsule products. Teva Counterclaims, ¶ 70. The removal of the product code for the discontinued capsule in the NDDF book did not prevent Teva, Impax, or anyone else from selling a fenofibrate capsule. Teva Counterclaims, ¶¶ 73-74, 79. Nor did it prevent a physician from writing a prescription for another manufacturer's capsule product. As Plaintiffs admit, the only effect is that a pharmacist could not automatically dispense a generic copy if a physician wrote a prescription for the discontinued TriCor product. Teva Counterclaims, ¶ 78.

Recognizing that the new TriCor tablet product was an improvement on its 200 mg capsule Lofibra product, Teva filed an ANDA directed at the new Abbott TriCor product and submitted Paragraph IV certifications claiming non-infringement. Teva Counterclaims, ¶ 46. In October 2002 Defendants filed an action in this Court alleging infringement of, *inter alia*, the '405 patent. Teva

Counterclaims, ¶ 47.[3] In November 2003 the '881 patent issued, and was similarly the subject of challenge and litigation. Teva Counterclaims, ¶ 55. The FDA granted tentative approval to Teva's 160 mg and 54 mg tablet formulations on March 5, 2004. Teva Counterclaims, ¶ 56. The statutory 30-month Hatch-Waxman stay relating to the '405 patent expired on March 2, 2005. Teva Counterclaims, ¶ 52.

III. Defendants' Second-Generation Tablets

One of the drawbacks of the 200 mg capsule and the 160 mg TriCor tablet was that they had to be taken with food. This was necessary to achieve the desired bioavailability and was required as part of TriCor's FDA-approved labeling. As Plaintiffs admit, nearly one-third of patients taking TriCor were not compliant with the labeling instruction. Teva Counterclaims, ¶ 98.

As part of their continuing drive to improve their product offering, the Defendants invested in technology from Elan and developed a further improved fenofibrate. Consolidated Direct Purchaser Complaint, ¶ 110. The result was a new formulation introduced in 2004 that (i) had a lower dosage of fenofibrate (48 mg and 145 mg) and, (ii) as indicated by its FDA-approved label, did not need to be taken with food (the "NFE Introduction"). Teva Counterclaims, ¶¶ 86, 98. Plaintiffs concede that this tablet incorporates an expanded FDA label with fewer limitations on administration than the old tablet product.[4] Teva Counterclaims, ¶ 98; Impax Counterclaims, ¶ 59. Teva alleges that the new NFE tablet was not an improvement because the "Indications" section of the label is "word-for-word identical"

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[3] Shortly after the PTO issued the '552 patent to Fournier in July 2003, Defendants listed the '552 patent in the Orange Book, Teva amended its ANDA to include a Paragraph IV certification for the '552 patent, and Defendants added the '552 claim to the patent litigation. Teva Counterclaims, ¶¶ 49-51. The '881 patent was added to the Orange Book listing but, by operation of law, no additional 30-month stay was granted as a result of the assertion of the '881 patent. Teva Counterclaims, ¶¶ 53, 55.

[4] Since Teva introduced selected parts of the product labels in its pleading, this Court may consider the *entire* labels, which portray a far different picture than the one Teva attempts to draw through selective disclosure. *See Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993) ("We now hold that a court may consider an undisputably authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document.").

to that same section in the label for the older TriCor tablet. Teva Counterclaims, ¶ 86. Teva ignores the "Dosage and Administration" sections of the product labels. Whereas the label for the 54 and 160 mg tablets states that they "should be given with meals, thereby optimizing the bioavailability of the medication," the label for the NFE tablets states that the product "can be given without regard to meals." Copies of the full FDA product labels are attached hereto as Exhibit 2.

In late 2004, Abbott discontinued selling its older tablet version and detailed the new product to physicians. Teva Counterclaims, ¶ 87. In May 2005, Abbott informed the NDDF that it was only selling its new tablet formulation. Teva Counterclaims, ¶ 90. This latest-generation version of TriCor is sold by Abbott today.

IV. The Tablet Litigation

This Court held its *Markman* hearing on the claim construction in February 2005, and on May 6, 2005, ruled on the motions for summary judgment. This Court found in favor of Abbott and Fournier and set for trial claim 6 of the '405 patent and claims 5, 10, 19, 26, 31, and 41 of the '881 patent. *Abbott Labs. v. Impax Labs., Inc.*, No. 03-120-KAJ (consolidated) 2005 U.S. Dist. LEXIS 8279 (D. Del. May 6, 2005) (attached as Exhibit 3; *Abbott Labs. v. Teva Pharm., Inc.*, No. 02-1512-KAJ (consolidated), 2005 U.S. Dist. LEXIS 8285 (D. Del. May 6, 2005) (attached as Exhibit 4). Because the TriCor tablet that Teva and Impax sought to copy was no longer being marketed, Abbott and Fournier voluntarily dismissed their patent litigations. Teva Counterclaims, ¶ 92. Plaintiffs sent a letter to this Court announcing this decision on May 16, 2005. Teva Counterclaims, ¶ 91. The FDA issued final approval of Teva's tablet ANDA on May 13, 2005. Teva Counterclaims, ¶ 59.[5] Teva has not yet introduced a fenofibrate tablet. Impax will be eligible to market a fenofibrate tablet upon expiration of Teva's Hatch-Waxman exclusivity period in November 2005. Impax Counterclaims, ¶ 64.

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[5] The stay of approval of Teva's tablet ANDA generated by the patent infringement suit regarding the '726, '670, and '405 patents had already expired in March 2005. Teva Counterclaims, ¶ 52.

ARGUMENT

I. Legal Standard.

Under Federal Rule of Civil Procedure 12(b)(6), the Court should grant a motion to dismiss if, accepting all the well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to plaintiff, the complaint fails to state a claim upon which relief may be granted. *See Doug Grant, Inc. v. Greate Bay Casino Corp.*, 232 F.3d 173, 183 (3d Cir. 2000). While this standard of review requires the Court to accept as true all factual allegations in the complaint, the Court need not accept as true unsupported conclusions and unwarranted inferences. *Id.* at 183-84.

Moreover, a court may take judicial notice of certain facts, such as prior proceedings in the case, what documents were filed, a position taken by one of the parties, or an admission or allegation made "as long as it is not unfair to a party to do so and does not undermine the trial court's factfinding authority." *In re Indian Palms Assocs., Ltd.*, 61 F.3d 197, 205 (3d Cir. 1995); *see also Werner v. Werner*, 267 F.3d 288, 295 (3d Cir. 2001) ("A court may take judicial notice of an adjudicative fact if that fact is not subject to reasonable dispute." Such a judicially noticed fact "must either be generally known within the jurisdiction of the trial court, or be capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned.").

II. Plaintiffs' Product Introduction Allegations Do Not State A Claim Under The Antitrust Laws.

Plaintiffs' allegations regarding Defendants' Product Introductions fail to state a claim under the antitrust laws. The antitrust laws are intended to promote new product development, and courts evaluating claims that a company has violated the antitrust laws by introducing a new product routinely reject such claims. In this case, Plaintiffs' Product Introductions claims fail because: (i) they cannot and do not allege that anyone is actually foreclosed from selling a fenofibrate product; and (ii) Plaintiffs' pleadings acknowledge that the new products had certain improved features over the then-existing versions.

A. The Antitrust Laws Encourage New Product Development.

The antitrust laws are intended to foster innovation, including new and improved versions to existing products. *Foremost Pro Color, Inc. v. Eastman Kodak Co.*, 703 F.2d 534, 546 (9th Cir. 1983) ("That the dominant firm in any market may through technological innovation expand its market share, increase consumer brand identification, or create demand for new products is perfectly consistent with the competitive forces that the Sherman Act was intended to foster."), *overruled on other grounds by Hasbrouck v. Texaco, Inc.*, 842 F.2d 1034 (9th Cir. 1987); *David L. Aldridge Co. v. Microsoft Corp.*, 995 F. Supp. 728, 753 (S.D. Tex. 1998) ("The antitrust laws do not require a competitor to maintain archaic or outdated technology; even monopolists may improve their products.").[6]

Courts confronted with this issue routinely reject antitrust claims based on new product introductions. For example, in *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263 (2d Cir. 1979), Berkey Photo sued Kodak over Kodak's simultaneous offering of a new pocket-size camera and film. Berkey claimed that it was injured because Kodak's introduction of the new system reduced Berkey's ability to sell its photofinishing services, which were then limited to developing the older types of film, and further alleged that the new film was a technical sham specifically designed to establish Kodak's monopoly in the new pocket camera market. The court rejected plaintiff's theory, noting that "[t]he attempt to develop superior products is, as we have explained, an essential element of lawful competition." *Id.* at 286; s*ee also Transamerica Computer Co. v. IBM Corp.*, 481 F. Supp. 965, 1005

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[6] It is widely recognized that any rule adopted to regulate business conduct should be carefully crafted so as not to chill innovation. *See Verizon Commc'n v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 414 (2004) (cautioning that "[m]istaken inferences and the resulting false condemnations are especially costly, because they chill the very conduct the antitrust laws are designed to protect.") (internal quotations omitted); 3A Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application*, ¶ 781a (2000 & 2005 Supp.) ("[N]o responsible commentator proposes to subordinate the public and consumer interest in better products to the preservation of less inventive rivals."); Herbert Hovenkamp, *Frank E. Strong Law Forum Lecture: The Monopolization Offense*, 61 Ohio St. L.J. 1035, 1037 (2000) ("[U]nmatched innovation may injure rivals so severely that they are forced to exit from the market, but we would hardly want an antitrust policy that condemns innovation itself as unlawful exclusion.").

(N.D. Cal. 1979 (finding that IBM's new interface formats were not a technical sham despite evidence that the "predominant intent" of the innovation "was undoubtedly to preclude or delay" rival competition), *aff'd*, 698 F.2d 1377 (9th Cir. 1983).

California Computer Prods., Inc. v. IBM, 613 F.2d 727 (9th Cir. 1979), presents another similar example. There, the plaintiff alleged that IBM's new disk drive interface design constituted "'technological manipulation' which did not improve performance" but instead foreclosed plaintiff from immediately competing in the same market. *Id.* at 744. The court rejected plaintiff's claim, concluding that:

> IBM, assuming it was a monopolist, had the right to redesign its products to make them more attractive to buyers whether by reason of lower manufacturing costs and price or improved performance. It was under no duty to help [plaintiff] or other peripheral equipment manufacturers to survive or expand. IBM need not have . . . constricted its product development so as to facilitate sales of rival products.

Id. *See also Foremost*, 703 F.2d at 543-45 (rejecting plaintiff's monopoly claim based on continued innovations) ("Kodak need not have constricted its product development so as to facilitate sales of rival products.") (internal quotations omitted); *Telex Corp. v. IBM*, 367 F. Supp. 258 (N.D. Okla. 1973) (finding for innovator on claim of predatory innovation), *rev'd on other grounds*, 510 F.2d 894 (10th Cir. 1975); *ILC Peripherals Leasing Corp. v. IBM*, 458 F. Supp. 423 (N.D. Cal. 1978) (same).[7]

Leading antitrust law scholars are in accord with courts ruling in favor of new product introductions, even if the effect is to disadvantage less innovative rivals. *See, e.g.,* Areeda & Hovenkamp, *supra*, ¶ 776d (no liability unless "the innovator knew before introducing the improvement into the market that it was *absolutely no better* than the prior version, and that the *only* purpose of the innovation

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[7] In *C.R. Bard, Inc. v. M3 Sys., Inc.*, the court never actually reached the question of plaintiff's new foreclosure theory. 157 F.3d 1340, 1382 (Fed. Cir. 1998) ("the legal sufficiency of the jury charge on the antitrust issues is not properly before us on appeal"), *reh'g en banc denied*, 161 F.3d 1380 (Fed. Cir. 1998) ("[T]his case does not establish or endorse a new antitrust theory."). As a result, *Bard* does not represent a departure from the general rule favoring new product introduction.